

In the Claims

Listing of the Claims

This listing of claims will replace all prior versions, and listings, of the claims in the application.

1. (Original) An aerosol formulation comprising a biodegradable microsphere of average diameter of from 0.5 to 5 μ m comprising a non-living reagent that produces a protective immune response in a mammal to whom it is administered.

2. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 1 wherein the said non-living reagent is antigenic polypeptide or a nucleic acid sequences which may encode such a polypeptide.

3. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 2 wherein the said non-living reagent is a sub-unit vaccine.

4. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ wherein the said non-living reagent is diphtheria toxoid, tetanus toxoid, *Botulinum* toxin FHC, *Bacillus anthracis* protective antigen (PA) or a polypeptide which is capable of generating a protective immune response against *Yersinia pestis*.

5. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 4 wherein the non-living reagent is the V antigen of *Y. pestis* or an immunologically active fragment thereof or a variant of these, or the F1 antigen of *Y. pestis* or an immunologically active fragment thereof or a variant of these, or a combination of these.

6. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ wherein the microspheres have an average diameter of less than 3 μ m.

7. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 6 wherein the microcapsules have an average diameter of between 1 and 1.5 μ m.

8. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ wherein the microspheres comprise a biodegradable polyester.

9. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 8 wherein the polyester comprises comprise Poly-lactide (PL).

10. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ wherein the microcapsules are lyophilised.

11. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ wherein the non-living reagent is encapsulated within the microspheres.

12. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ which further comprises the non-living reagent in free form.

13. (Currently Amended) ~~A~~The formulation ~~according to~~of claim 12 wherein the ratio of the amounts of the free reagent to the reagent associated with the microspheres is in the range of from 1:20 to 2:1.

14. (Currently Amended) ~~A~~The formulation ~~according to any one of the preceding claims of claim 1~~ in unit dosage form.

15. (Currently Amended) A nebulizer or inhaler comprising a formulation ~~according to any one of the preceding claims of claim 1~~.

16. (Cancelled)

17. (Currently Amended) A method of producing a protective immune response in a mammal in need thereof, said method comprising administering to the lung of said

mammal, a protective amount of an aerosol formulation according to any one of claims 1 to 4 of claim 1.